



Doc Code: AP.PRE REQ

PTO/SB/33 (07-05)

Approved for use through xx/xx/200x. OMB 0651-00xx

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

9362-4

CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number EV 675789889 US

Date of Deposit: August 19, 2005

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Erin A. Campion

Application Number

10/662,621

Filed

September 15, 2003

First Named Inventor

Michael S. Williams

Art Unit

1615

Examiner

Levy, Neil S.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☒ attorney or agent of record.
Registration number 40,519☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34


Signature

Needham James Boddie, II

Typed or printed name

(919) 854-1400

Telephone number

August 19, 2005

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



**RESPONSE UNDER 37 C.F.R. 1.116 - EXPEDITED
PROCEDURE - EXAMINING GROUP 1615**

Attorney Docket No. 9362-4

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: Williams *et al.*
Application Serial No.: 10/662,621
Filed: September 15, 2003

Confirmation No. 9764
Group Art Unit: 1615
Examiner: Neil S. Levy

For: **CARBON DIOXIDE-ASSISTED METHODS OF PROVIDING
BIOCOMPATIBLE INTRALUMINAL PROSTHESES**

Date: August 19, 2005

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

This document is submitted in support of the Pre-Appeal Brief Request For Review filed concurrently with a Notice of Appeal for the above-referenced patent application. No amendments are being filed with this Request.

If any extension of time for the accompanying response or submission is required, Applicants request that this be considered a petition therefor. The Commissioner is hereby authorized to charge any additional fee, which may be required, or credit any refund, to Deposit Account No. 50-0220.

REMARKS

Applicants hereby request a Pre-Appeal Brief Review of the finally rejected claims which have been amended, but refused entry by the Examiner. This request notes the clear error on behalf of the Examiner.

A. Final Office Action

In a Final Office Action (the "Final Action"), mailed May 4, 2005, Claims 1-26 were pending and Claims 1-7, 11, 14-19, 22 and 26 were rejected under 35 U.S.C. §102(b) as being anticipated by Journal Article "Active growth factor delivery from poly(D,L-lactide-coglycolide) foams prepared in supercritical CO₂" by David D. Hile *et al.* ("Hile"). Claims 8-10, 12, 13, 20, 21 and 23-25 were indicated by the Examiner as being allowable if rewritten in

independent form including all of the limitations of the base claim and any intervening claims.

B. First Response to Final Office Action

In a Response transmitted to the Examiner via facsimile transmission on May 17, 2005, Applicants rewrote Claims 8-10, 12, 13, 20, 21 and 23-25, all of which were indicated in the Final Action to be allowable, in independent form as follows:

Claim 8 was rewritten in independent form as amended Claim 1, and original Claim 8 was cancelled.

Claim 9 was rewritten in independent form as new Claim 27, and new dependent Claims 28-35 were added which depend therefrom. Original Claim 9 was cancelled.

Claim 10 was rewritten in independent form as new Claim 36, and new dependent Claims 37-44 were added which depend therefrom. Original Claim 10 was cancelled.

Claim 12 was rewritten in independent form as new Claim 45, and new dependent Claims 46-51 were added which depend therefrom. Original Claim 12 was cancelled.

Claim 13 was rewritten in independent form as new Claim 52, and new dependent Claims 53-60 were added which depend therefrom. Original Claim 13 was cancelled.

Claim 20 was rewritten in independent form as amended Claim 15, and original Claim 20 was cancelled.

Claim 21 was rewritten in independent form as new Claim 61, and new dependent Claims 62-67 were added which depend therefrom. Original Claim 21 was cancelled.

Claim 23 was rewritten in independent form as new Claim 68, and new dependent Claims 69-72 were added which depend therefrom. Original Claim 23 was cancelled.

Claim 24 was rewritten in independent form as new Claim 73, and new dependent Claims 74-79 were added which depend therefrom. Original Claim 24 was cancelled.

Claim 25 was rewritten in independent form as new Claim 80, and new dependent Claims 81-86 were added which depend therefrom. Original Claim 25 was cancelled.

C. First Advisory Action

In a first Advisory Action, mailed May 31, 2005, the Examiner refused entry of the rewritten independent claims and claims depending therefrom on the following grounds:

1) The rewritten claims raised new issues that would require further consideration and/or search;

2) "Applicant's arguments were not convincing, as some claims are now broader than previously rejecte [sic] (claim 27, for example). Further consideration of the enlarged subject matter would necessitate reconsideration & re-search."

3) The rewritten claims are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and

4) The rewritten claims present additional claims without canceling a corresponding number of finally rejected claims.

The Examiner is clearly in error. The rewritten claims do not raise any new issues that require further consideration and/or search. Applicants merely rewrote claims in independent form **as suggested by the Examiner**. Moreover, none of the rewritten claims are broader than before; in fact, they have been rewritten in independent form that included the limitations of the base claim and any intervening claims. The Examiner specifically identifies Claim 27 as being broader in its rewritten form. Original Claim 9 is rewritten below in "red-line" format to clearly indicate that new Claim 27 is not broader than original Claim 9.

27. 9. ~~The method of Claim 1, wherein the intraluminal prosthesis is a~~ A method of producing a biocompatible stent for *in vivo* use, comprising:
providing a stent having a portion thereof formed from polymeric material, wherein the polymeric material contains one or more toxic materials;
immersing the polymeric material in a densified carbon dioxide composition such that the toxic materials are absorbed by the densified carbon dioxide composition; and
removing the densified carbon dioxide composition containing the toxic materials from the polymeric material, such that the stent is suitable for *in vivo* use.

The rewritten claims do, in fact, place the application in better form for appeal because the claims indicated by the Examiner as being allowable if rewritten in independent form including the limitations of the base claim and any intervening claims **have** been rewritten in independent form including the limitations of the base claim and any intervening claims.

Finally, the rewritten claims do not present additional claims without canceling a corresponding number of finally rejected claims. Applicants merely rewrote claims in

independent form as suggested by the Examiner. For claims rewritten in independent form as new independent claims, dependent claims were added. However, these dependent claims are by definition narrower than the independent claim from which they depend. As such, if the independent claim is indicated as being allowable by the Examiner, the dependent claims should also be allowable.

D. Telephone Conference with Examiner

In a telephone conversation with the Examiner on June 9, 2005, the undersigned discussed each of the rewritten claims and explained how they were not broader than the originally rejected claims. The Examiner indicated that he no longer received a working paper file and that it was difficult to review the claims on-line via a computer. Even though the undersigned clearly indicated how each claim had been amended, the Examiner maintained it was too difficult to review the claims without a paper copy. The undersigned offered to send the Examiner a paper copy of the claims in marked-up format indicating the changes made, but this offer was rejected.

E. Substitute Response to Final Action

In a Response transmitted to the Examiner via facsimile transmission on June 23, 2005, Applicants rewrote Claims 8-10, 12, 13, 20, 21 and 23-25 in independent form without adding any "new" independent claims and without adding any dependent claims. For example, Claim 8 was amended into independent form, rather than rewriting Claim 8 in independent form as amended Claim 1. In addition, original independent Claims 1 and 15 were cancelled.

F. Second Advisory Action

In a second Advisory Action, mailed July 15, 2005, the Examiner refused entry of the rewritten independent claims in the substitute response of June 23, 2005. The Examiner appears to reject the claims on substantive grounds, but fails to clearly indicate what grounds the rejection is based on. The Examiner merely states that "reconsideration poses realization that what is claimed is a method, and at the very least, Greiner(Hercules) shows it. The results

In re Application: Williams *et al.*
Application Serial No.: 10/662,621
Filed: September 15, 2003
Page 5 of 5

as claimed would be necessitated by the processes of Greinere [sic]."

CONCLUSION

Applicants submit that the Examiner erred in rejecting the amended claims that were rewritten in independent form in the Response of May 17, 2005 and in the response of June 23, 2005. Applicants have tried several times to amend claims indicated as being allowable by the Examiner by rewriting these claims in independent form. Accordingly, Applicants submit that the present application is not in condition for appeal because of clear error on the part of the Examiner, and request that the application be passed to issuance based on the amended claims in the Response of May 17, 2005.

Respectfully submitted,



Needham James Boddie, II
Registration No. 40,519

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401
Doc. No. 454621

CERTIFICATE OF EXPRESS MAILING

Express Mail Label No.: **EV 675789889 US**
Date of Deposit: **August 19, 2005**

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Erin A. Campion